Exhibit AA



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Westbrook

Serial No.: 07/784,222

Filed: October 28, 1991

For: METHODS AND COMPOSITIONS

FOR THE DETECTION OF

CHROMOSOMAL ABERRATIONS

Examiner: J. Fredman

Group Art Unit: 1634

Atty. Dkt: ARCD-010/NAK

CERTIFICATE OF MAILING 37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C.

20231, on the date below:

3cph 1, 1996

Date

Richard A. Nakashima

DECLARATION UNDER RULE 131

I, CAROL A. WESTBROOK, HEREBY DECLARE AS FOLLOWS:

- 1. I am the named inventor of the subject matter claimed in the referenced U.S. patent application, Serial No. 07/784,222, filed October 28, 1991.
- 2. I understand that the Patent and Trademark Office Examiner in charge of examining this application has cited against my application the following publication:

Tkachuk et al., "Detection of bcr-abl Fusion in Chronic Myelogeneous Leukemia by in Situ Hybridization," Science 250: 559-562, 1990.

- 3. The invention of claims 1-3 and 5-35 was made and tested in the United States prior to October 26, 1990, and therefore prior to publication of the cited article by Tkachuk *et al*.
- 4. The fact that the invention of claims 1-3 and 5-35 was made and tested in this country prior to October 26, 1990 is evidenced by studies set forth in the attached notebook extracts (Exhibit A). Among other things, this Exhibit sets forth the following studies which exemplify the practice of my invention:
 - a) Possession and use of the c-Hu-ABL, PEM12 and MSB-1 probes in *in situ* hybridization experiments for detection of chromosomal aberrations in leukemic cell lines and in blood cells from patients with leukemia (Pages 1-2 and 5-43 of Exhibit A).
 - b) Identification of doublets in the chromosomal DNA of leukemic cell lines and blood cells from patients with leukemia using distinguishably labeled probes specific for the c-H-abl and bcr genes. (Pages 1-2, 5-6 and 21-24 of Exhibit A).
 - c) A detailed protocol for detection of the c-H-abl/bcr fusion gene, using distinguishably labeled probes specific for the c-H-abl and bcr genes. (Pages 5, 7-11, 13-22, 24, 26-31, 33-43 of Exhibit A).

Each of items a) through c) as represented in the attached Exhibit were carried out in this country prior to October 26, 1990.

5. All statements made in this Declaration of my own knowledge are true and all statements made in this Declaration on information and belief are believed to be true, and these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both under 18 U.S.C. §1001 and may jeopardize the validity of this application or any patent issuing thereon.

Date 3 78

Carol A. Westbrook